IRISH MEDICINES BOARD ACT 1995

EUROPEAN COMMUNITIES (ANIMAL REMEDIES) REGULATIONS 2007

(S.I. No. 144 of 2007)

VPA: **10021/039/001**
Case No: 7003497

The Irish Medicines Board in exercise of the powers conferred on it by Animal Remedies Regulations (S.I. No. 144 of 2007) hereby grants to:

Bayer Limited

Animal Health Division, **The Atrium, Blackthorn Road**, **Dublin 18**, **Ireland**

an authorisation, subject to the provisions of the said Regulations and the general conditions of the attached authorisation, in respect of the Veterinary Medicinal Product:

Bayer Dog Wormer Tablets

The particulars of which are set out in Part 1 and Part 2 of the said Schedule. The authorisation is also subject to any special conditions as may be specified in the said Schedule.

Signed on behalf of the Irish Medicines Board

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A person authorised in that behalf by the said Board.

(NOTE: This authorisation replaces any previous authorisation in respect of this product which is now null and void.)

Part II

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Bayer Dog Wormer Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Active Substances	
Febantel	150 mg
Pyrantel embonate	144 mg
Praziquantel	50 mg

3 PHARMACEUTICAL FORM

Tablet

4 CLINICAL PARTICULARS

4.1 Target Species

Dogs

4.2 Indications for use, specifying the target species

For the control of the following roundworms and tapeworms in dogs and puppies:

Ascarids:	Toxocara canis, Toxascaris leonina (adult and late immature forms)
Hookworms:	Uncinaria stenocephala, Ancylostoma caninum (adults)
Whipworms:	Trichuris vulpis (adults)
Tapeworms:	Echinococcus spp. Taenia spp. and Dipylidium caninum (adult and immature forms)

4.3 Contraindications

Do not use simultaneously with piperazine compounds.

4.4 Special warnings for each target species

As a precautionary measure to prevent the establishment of *Echinococcus multilocular*is in the UK and Ireland, it is recommended that all dogs and cats entering the country be treated with praziquantel.

4.5 Special precautions for use

Any part-used tablets should be discarded.
Do not exceed the stated dosage when treating pregnant bitches.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

Consult a Veterinary surgeon before treating pregnant animals for roundworms (see also Section 4.2) above.
Bayer Dog Wormer may be used during lactation (see Section 4.8 below).

4.8 Interaction with other medicinal products and other forms of interaction

Do not use simultaneously with piperazine compounds.

4.9 Amounts to be administered and administration route

Dosage

The recommended dose rates are: 15 mg/kg bodyweight febantel, 14.4 mg/kg pyrantel and 5 mg/kg praziquantel. This is equivalent to 1 tablet per 10 kg bodyweight.

Administration and Duration of Treatment

Oral administration, the tablet(s) can be given directly to the dog or disguised in food. No starvation is needed before or after treatment.

For routine treatment a single dose is recommended.

Puppies should be treated at 2 weeks of age and every 2 weeks until 12 weeks of age. Thereafter they should be treated at 3 month intervals. It is advisable to treat the bitch at the same time as the puppies. Drontal Puppy Suspension may prove a more convenient product in puppies and young dogs up to one year of age where treatment is required for roundworms only.

For the control of Toxocara, nursing bitches should be dosed 2 weeks after giving birth and every 2 weeks until weaning.

For routine control adult dogs should be treated every 3 months. In the event of a heavy roundworm infestation, a repeat dose should be given after 14 days.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

Bayer Dog Wormer Tablets are well tolerated in dogs. In safety studies doses of 5x or greater gave rise to occasional vomiting.

4.11 Withdrawal Period(s)

Not applicable.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

The product contains anthelmintics active against roundworms and tapeworms. The product contains three active substances:
1. Febantel, chemical name: [2-[(Methoxyacetyl)amino]-4-(phenylthio)phenyl]carbonimidoyl]biscarbamic acid dimethyl ester
2. Pyrantel embonate (pamoate), a tetrahydropyrimidine derivative with the following chemical name: (E)-1,4,5,6-Tetrahydro-1-methyl-2-[2-(2-thienyl)ethyenyl] pyrimidine, and
3. Pyraziquantel, a partially hydrogenated pyrazino-isoquinoline derivative used widely as an anthelmintic for both human and veterinary use. The chemical name for this third substance is 2-(Cyclohdexyl-carbonyl)-1,2,3,6,7,11b-hexahydro-4H-pyrazino-[2,1-a]isoquinolin-4-one.

In this fixed combination product pyrantel and febantel act synergistically against all relevant nematodes (ascarids, hookworms and whipworms) in dogs. In particular, the activity spectrum covers Toxocara canis, Toxascaris leonina, Uncinaria stenocephala, Ancylostoma and Trichuris vulpis.

The spectrum of activity of praziquantel covers all important cestode species in dogs, in particular all Taenia spp, Dipylidium caninum, Echinococcus granulosus and

Echinococcus multilocularis. Praziquantel acts against adult and immature forms of these parasites.

Pyrantel acts as a cholinergic agonist. Its mode of action is to stimulate nicotinic cholinergic receptors of the parasite, induce spastic paralysis and thereby allow removal from the gastro intestinal (GI) system by peristalsis.

Within the mammalian system febantel undergoes ring closure forming fenbendazoles and oxfendazole. It is these chemical entities which exert the anthelmintic effect by inhibition of tubulin polymerization. Formation of microtubules is thereby prevented, resulting in disruption to structure vital to the normal functioning of the helminth. Glucose uptake, in particular, is affected, leading to a depletion in cell ATP. The parasite dies upon exhaustion of its energy reserves, which occurs 2-3 days later.

Praziquantel is very rapidly absorbed and distributed throughout the parasite. Both in vivo and in vitro studies have been shown that praziquantel causes severe damage to the parasite integument, resulting in contraction and paralysis. There is an almost instantaneous tetanic contraction of the parasite musculature and a rapid vacuolization of the syncytial tegument. This rapid contraction has been explained by changes in divalentcation fluxes, especially calcium.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

As per VPA 10021/14/1

6.2 Incompatibilities

None known.

6.3 Shelf-life

5 years.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and composition of immediate packaging

Container Material:	Polyethylene-coated aluminium foil
Container Colour:	White
Container Sizes:	Cartons containing 2, 20 and 100 tablets.
Container Contents:	Pale yellow tablets.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

Any unused product or waste material should be disposed of in accordance with national requirements

7 MARKETING AUTHORISATION HOLDER

Bayer Limited,
Animal Health Division,
The Atrium,
Blackthorn Road,
Dublin 18

8 MARKETING AUTHORISATION NUMBER(S)

VPA No. 10021/39/1

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

2nd October 2005

10 DATE OF REVISION OF THE TEXT

19th July 2007